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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,565	11/13/2003	Harvey A. Fishman	S02-296/US	8264

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LUMEN INTELLECTUAL PROPERTY SERVICES, INC.
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EXAMINER

FORD, ALLISON M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,565

Applicant(s)

FISHMAN ET AL.

Examiner

Allison M. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-41 and 43-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-41 and 43-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendments

Applicant's amendments filed 3 February 2006 to claims 39, 44, 48 and 57 have been entered. Claim 42 has been cancelled. Claims 39-41 and 43-61 remain pending in the current application, all claims have been considered on the merits. All arguments have been fully considered, but are moot in view of the new grounds of rejection set forth below.

Priority

Acknowledgement is made of applicant's claim for priority as a CIP of US application 10/184,210 filed 06/27/2002, which further claims priority to provisional application 60/301,934 filed 06/29/2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-41 and 43-61 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The present application does not disclose specific means for fabricating the claimed devices for modulating neuronal activity, rather they focus on the specifics of the individual components of the devices; however, as a continuation-in-part, the parent application 10/184,210 (now US Patent 7,001,608) is incorporated in its entirety into the present application, and the parent application does teach specific methods and procedures for fabricating the claimed devices. While it is satisfactory to rely on the parent application for information regarding the claimed device, it is noted that in the parent application

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discloses that that is it critical for the artificial synapse chip to be oxidized on all surfaces and then coated with a polyimide layer in order to reduce capacitance; the parent application teaches it is critical to reduce the capacitance of the artificial synapse chip for proper function (See appln 10/184,210 Pg. 31-33).

Therefore it appears that it is also critical for the currently claimed devices to be oxidized and coated with a polyimide layer in order to reduce capacitance; such must be clearly stated in the claims so as to clearly claim and describe the invention.

Claims 39-31 and 43-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as their invention.

The devices of claims 39, 44, 48 and 61 all require a flow regulator to be in operable relationship with fluid in the reservoir for moving fluid to the aperture; however, the independent claims, and their dependents, fail to particularly point out and distinctly claim what the 'flow regulator' consists of and thus fail to accurately describe the claimed invention. Claims 57-60, directed to using the claimed devices, are also rendered indefinite for the same reasons, as the device, critical to practice of the methods, are not clearly claimed. In giving the term 'flow regulator' its broadest reasonable interpretation one of ordinary skill in the art could interpret 'flow regulator' to be merely be the aperture itself, for, as submitted by applicant, the size and shape of the aperture does function to regulate the flow from the reservoir to the surface (See specification Pg. 15, paragraph 00062). The specification teaches the flow regulator to be a pump, which can be a mechanical pump, acoustic pump, electric pump, magnetic pump, or electroosmotic pumps (See Specification Pg. 16-17, paragraph 00068); the specification provides examples and teachings in depth regarding the form and function of the different pumps which can be utilized as the flow regulators. Therefore it appears to be critical to the invention that the flow regulators be correctly identified as pumps, either mechanical or non-mechanical in

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structure, which actively delivery the fluid from the reservoir to the aperture; thus such must be clearly conveyed in the claim language. It is noted that some claims do further teach the flow regulator to be an electrically controlled, or electromechanical device, which may be controlled by photodiodes, but these claims still fail to accurately describe the flow regulator as a pump as taught by the specification.

Applicants' claim 46 requires the device of claim 44 to further comprise at least one photodiode. The claim is indefinite because it fails to describe the structural relationship of the photodiode. According to the specification photodiodes are included to provide an electrical source for the flow regulator pump (See current specification, Pg. 16, paragraph 00068 & Pg. 19, paragraph 00077). Claim 46 fails to clearly convey the photodiodes are utilized as the electrical source for actuating the electrically controlled flow regulator.

Applicant's claim 47 is indefinite because it requires a well to be connected to the reservoir via the aperture; however parent claim 44 requires a channel to connect the reservoir to the aperture. Therefore, it appears the connection between the well and the reservoir involves both the aperture and the channel.

Please note that the language of a claim must make it clear what subject matter the claim encompasses to adequately delineate its "metes and bounds." See, e.g., the following decisions: In re Hammack, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); In re Venezia 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: In re Steele, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); In re Moore 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); In re Merat, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39, 43-45, 48, 49, 52 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iezzi et al (US Patent 6,668,190), which is fully supported by provisional application 60/212,214, in view of Lu et al (Biomaterials, 1999), and further in view of Mallapragada et al (US Patent 6,676,675) and Yang et al (US Patent 6,071,597).

Iezzi et al teach a drug delivery device for stimulating neurological tissue, in particular for the stimulation of neuronal tissue in the retina, and a method for using the device to stimulate the neurological tissue.

The device of Iezzi et al comprises a chip comprising two major surfaces and one minor surface (which applicant calls a housing). The major surface of the chip is intended to be in contact with neurological tissue containing neurological cells, thus the major surface is biocompatible with at least a portion of a neuronal cell. The device further comprises a reservoir that is connected to the chip by microfluidic channels, the microfluidic channels end in conduits that open onto the major surface of the chip (at what applicant calls apertures on the surface). The device further comprises a pump (which applicant calls a flow regulator) which functions to pass fluid in the reservoirs through the microfluidic channels to the major surface of the chip (See col. 4, ln 10-col. 8, ln 34, especially col. 5, ln 42-col. 6, ln 32 & Fig. 3-5). The reservoirs hold neuro-active pro-drugs (which applicant calls bioactive agents); the neuro-active pro-drugs can include neurotransmitters (see col. 7, ln 11-13).

Iezzi et al further teach a method of using the device described above involving attaching the chip to the retina and delivering the bioactive solution to the chip, thereby stimulating the neuronal cells (See

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col. 8, ln 35-col. 9, ln 5). Iezzi et al teach that the bioactive drugs can comprise neurotransmitters (see col. 7, ln 11-13).

Though Iezzi et al do not teach providing micropatterns on the chip surfaces, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to micropattern the surfaces of the chip which are to come in contact with the neural cells in order to direct cell attachment, cell alignment, cell orientation and cell organization. In support see Lu et al. Lu et al teach micropatterned substrates with topological surface features modulate cell shape and function by directing cell growth along the micropattern to a desired destination or orientation. Lu et al further teach that use of micropatterned substrates are particularly useful in directing regeneration of neurological tissue in the eye, particularly retinal pigment epithelial cells, which are polar and must be properly aligned in order for successful function (See Lu et al, pg. 2351, col. 2- pg 2352, col. 1). Lu et al also teach methods for creating chemical or topographical micropatterns on substrates, including microcontact printing, and photolithographic treatments (See Lu et al, pg. 2352, col. 1).

One of ordinary skill in the art would have been motivated to micropattern the surfaces of the chips of Iezzi et al, as suggested by Lu et al, in order to direct cell growth and orientation along the micropatterns to the apertures where the neuro-active pro drugs are released. Lu et al teach that micropatterning can aide in attachment of cells to the substrate surface, such would clearly be desirable in the method of Iezzi et al, which requires contact of the neurological cells with the substrate. One would expect success micropatterning the chip surfaces of Iezzi et al because methods of creating micropatterns on cell substrates are well known in the art, as evidenced by Lu et al (Claims 39, 43-45 and 57-59)

Iezzi et al is also silent on the material of the device; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use flexible, biocompatible materials for the portions of the device, including the chip surfaces, the microfluidic channels and the pump (interpreted to include the 'housing of the pump'). One of ordinary skill in the art would have been

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motivated to use flexible materials for the chip surfaces because the chip is intended to be implanted in the retinal region of the eye; therefore in order to accommodate the curvature of each individual's eye, and well as movement and flexing of the eye muscles, the material of the implanted portion of the device needs to be flexible. One of ordinary skill in the art would have been motivated to use flexible materials for the microfluidic channels and pump because at least a portion of each of the materials is to be implanted within a subject; one of ordinary skill in the art will recognize that it is desirable to utilize flexible materials in *in vivo* applications so as to reduce discomfort and to increase ease of implantation. One would have had a reasonable expectation of success of creating the device of Iezzi et al out of completely flexible materials because flexible materials, such as silicon, poly (D, L-lactide), glycolic acids, glycolide trimethylene carbonate, polyester, polyglycolic acids, collagen, polylactic acid, poly(organo)phosphazine, polyorthoester, glycosaminoglycan, L-lactide, ε-caprolactone, polyurethane, polyimides, polystyrene, polyesters, polycarbonates, polytetrafluoroethylenes, and polysiloxane imides are well known in the art (See, e.g. Mallapragada et al col. 2, ln 40-65 & Yang et al, col. 7, ln 23-27) (Claims 48, 49, 52, 60 and 61). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

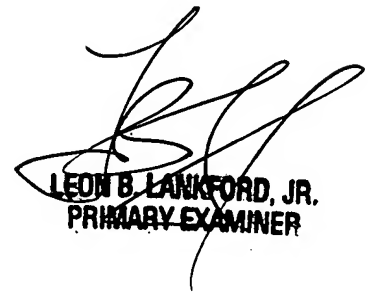
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651



LEON B. LANFORD, JR.
PRIMARY EXAMINER